FACTSHEET

# NTP CENTER FOR THE EVALUATION OF RISKS TO HUMAN REPRODUCTION

*Year 2001*

National Toxicology Program

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Research Triangle Park
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*headquartered at the*

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

NATIONAL INSTITUTES OF HEALTH

The NTP and the National Institute of Environmental Health Sciences have established the NTP Center for the Evaluation of Risks to Human Reproduction to serve as an environmental health resource to the public and to regulatory and health agencies. The Center provides scientifically based, uniform assessments of the potential for adverse effects on reproduction and development caused by agents to which humans may be exposed. This is accomplished through rigorous evaluations of the scientific literature by independent panels of scientists.

There is widespread concern among health professionals, environmental scientists, and the public that environmental exposures may be contributing to human reproductive disorders. Between five and ten percent of couples desiring children encounter problems achieving pregnancy, approximately 50 percent of pregnancies are not successfully completed, and 3 to 5 percent of newborns have major birth defects. The etiology of these problems is largely unknown. Thus, there is a clear need for readily accessible, scientifically authoritative evaluations of the human and experimental evidence that adverse effects on human reproduction and development may result from chemical exposures. The Center's goal is to provide such evaluations. A special effort is made to summarize these reports in terms that can be understood by those who are not scientifically trained.

Nominations of chemicals to be evaluated through the Center are solicited from the public and scientific communities, including industry, Federal, state, and local governments, academia, environmental groups, citizens, and workers.

Chemicals selected for evaluation are reviewed by expert panels of approximately 10-15 scientists selected for their expertise in various aspects of reproductive toxicology and other relevant areas. These panels develop reports addressing the possibility of reproductive health effects on humans exposed to a specific chemical or chemical mixture. Approximately 2-3 chemicals are evaluated each year. Panel meetings are open to the public and include the opportunity for public comment.

The goals of the individual assessments are to 1) interpret for and provide to the general public information about the strength of scientific evidence that a given exposure or exposure circumstance poses a hazard to reproduction and the health and welfare of children; 2) provide regulatory agencies with objective and scientifically sound assessments of reproductive/developmental health effects associated with exposure to specific chemicals or classes of chemicals, including descriptions of any uncertainties associated with the assessment of risks; and 3) identify knowledge gaps to help establish research and testing priorities.

Oversight for the Center is provided through the NTP Board of Scientific Counselors (BSC), a chartered peer review group of scientific experts primarily outside the government, who provide advice on priorities, directions, and the adequacy of the process and facilitate public input into the process.

## Review Process

The NTP Board of Scientific Counselors advises the Center on its processes, priorities, and direction. The Center follows an open process for nomination, selection, and review of chemicals. Public input is welcome throughout the process and can occur through 1) nomination of chemicals for evaluation, 2) submission of comments on the prioritizing and selecting of nominated chemicals, 3) submission of comments on the evaluation of a particular chemical at the time of an expert panel meeting, 4) nomination of scientists for

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the expert panels, and 5) submission of comments on the expert panel report. Nominations can come from interested individuals, Federal and State agencies, NTP staff, labor, and industry. A Core Committee, composed of representatives from NTP-participating agencies, reviews nominations and recommends candidate chemicals to the NTP. Subsequently, the Core Committee reviews dossiers prepared on the candidates by the Center and the public comments and submits a list of prioritized chemicals to the NTP for final selection. Chemicals are selected for review based upon several factors including production volume, extent of human exposures, public concern about chemical hazard, published evidence of reproductive or developmental toxicity, and evaluation of any additional information. An expert panel meets in a public session, reviews the scientific evidence on the chemical(s) under review, receives public comments, and then prepares a report on the chemical(s). NTP staff prepares a final NTP Center Report on the evaluated chemical(s) that integrates background information on the chemical(s), findings of the expert panel, public comments, and a discussion of any additional, recent studies. This final report is made publicly available and distributed to appropriate regulatory and health agencies.

**CERHR Web Site (http://cerhr.niehs.nih.gov)**

The Center's web site provides extensive information on the organization and activities of the CERHR. It includes the Center's reports, press releases, meeting announcements, and Federal Register Notices. It also provides a source of information on a wide range of common questions and concerns regarding fertility, healthy pregnancy, and the potential of various exposures to adversely affect normal development of the unborn child.

**Year 2000**

The Center's first evaluation was conducted over a one-year period by a 16-member Expert Panel made up of scientists from government, universities, and industry. The panel evaluated evidence that the seven selected phthalate esters listed below may pose a reproductive and/or developmental hazard for exposed humans. Phthalate esters are used as plasticizers in a wide range of polyvinyl chloride-based consumer products. These phthalate esters were selected for the initial evaluation by the CERHR based on their high production volume, extent of human exposures, use in children's products, published evidence of reproductive or developmental toxicity, and public concern. NTP staff will prepare an NTP Center Report that will integrate the findings of the expert panel and any recent relevant studies, and summarize public comments on the Expert Panel Reports. A 60-day public comment period on these reports was available from October 10 through December 11, 2000.

- butyl benzyl phthalate
- di(2-ethylhexyl) phthalate
- di-isodecyl phthalate
- di-isononyl phthalate
- di-n-butyl phthalate
- di-n-hexyl phthalate
- di-n-octyl phthalate

Expert Panel reports on the above phthalate esters can be obtained from the CERHR web site (http://cerhr.niehs.nih.gov).

**Year 2001**

An evaluation of methanol is underway and the meeting of the Methanol Expert Panel is anticipated to take place in the summer of 2001. Ethylene glycol, 1-bromopropane and 2-bromopropane are being considered for evaluation by subsequent Panels.

The NTP Center invites the nomination of chemicals or chemical mixtures for future evaluations and suggestions for scientists to be added to the Expert Registry. Nominations should be accompanied by the reason for the nomination and, whenever possible, appropriate background information, data, or literature citations. Suggestions for scientists to be added to the Expert Registry should be accompanied by a description of their expertise and curriculum vitae.

*Nominations, requests for expert panel reports and requests for further information should be forwarded to:*
*Dr. Michael Shelby, NIEHS, P.O. Box 12233, MD EC-32, Research Triangle Park, NC 27709*
*Phone: 919/541-3455 Or visit the CERHR Web Site at:* http://cerhr.niehs.nih.gov